

JAN 16 2004

Section 5

510 (k) SUMMARY

1. Applicant: Bisco, Inc
1100 West Irving Park Road
Schaumburg, IL 60193

Contact Person: Benjamin Lichtenwalner
Ph. 847-534-6146
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Prepared Date: November 12, 2003

2. Device Trade Name: DIAPEX

Common/Usual Name: Calcium/Iodoform Root Canal Treatment Paste

Classification/Name: Class II per 21 CFR 872.3820 Root Canal Filling Resin

3. Predicate Device: Vitapex Pre-loaded dental syringe from Neo Dental Chemical Products, cleared under K973667 dated 11/6/1997.

4. Description of Application Device:

DIAPEX is a yellow radiopaque calcium hydroxide paste with iodoform, used as a root canal filling material. It is packaged as a 2 gm syringe. Intraoral application uses enclosed disposable intracanal tips.

5. Intended Uses of Applicant Device:

DIAPEX is used to stimulate the healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients. DIAPEX is used to promote healing effects and to help prevent bacterial contamination of the canal, as the two main ingredients improve the induction effect for hard tissue induction and deposition. DIAPEX can also be used as a medicament for the treatment of infected root canals, and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete. The use of DIAPEX in the treatment of infected root canals, or following pulpectomy, or for the apexogenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha is also indicated.

6. Technological Characteristics:

Technological Characteristic	Vitapex	DIAPEX
Intended use	Root Canal Filling Material	Root Canal Filling Material
Chemical composition	Calcium Hydroxide / Iodoform Paste	Calcium Hydroxide / Iodoform Paste
Mechanical/ Physical properties	Yellow Radiopaque Paste	Yellow Radiopaque Paste

Side by side comparisons of **DIAPEX** to the predicate device **Vitapex** Pre-loaded dental syringe from Neo Dental Chemical Products clearly demonstrates that the applicant device is substantially equivalent to the legally marked device. It is concluded that the information supplied in this submission has proven the safety and efficacy of **DIAPEX**.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 16 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Benjamin Lichtenwalner
Regulatory Affairs Coordinator
Bisco, Incorporated
1100 West Irving Park Road,
Schaumburg, Illinois 60193

Re: K033585
Trade/Device Name: DIAPEX
Regulation Number: 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: November 12, 2003
Received: November 13, 2003

Dear Mr. Lichtenwalner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 –Mr. Lichtenwalner

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K033585

Indications for Use

510(k) Number (if known): **K033585**

Device Name: **DIAPEX**

Indications For Use:

1. For use to stimulate the healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients.
2. Used to promote healing effects and to help prevent bacterial contamination of the canal, as the two ingredients improve the induction effect for hard tissue induction and deposition.
3. To be used as a medicament for the treatment of infected root canals, and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete.
4. For use in the treatment of infected root canals, or following pulpectomy, or for the apexogenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha.

These indications include application in:

1. Intracanal Medicament
2. Apexification
3. Periapical Lesions
4. Root Resorption
5. Temporary Root Filling
6. Perforations
7. Underdeveloped pulpless teeth

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033585

Page 1 of 1